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Croatia

Biotechnology

Draft Law Bans Biotech Products

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Report Highlights: This draft law shows that Croatia is heading toward a ban on the importation, marketing, use, and production of the products of agricultural biotechnology. The ban would be in place until biotechnology is regulated by other, more specific legislation. The draft is dated September/October 2001. The draft law is just one aspect of the Croatian government's an anti-GMO policy. The government also conducted an anti-GMO ad campaign this summer promoting Croatia as a GMO-free tourist destination (see HR 1008).

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Vienna [AU1], HR

Begin Unofficial Translation of Draft Croatian Biotechnology Law

I. CONSTITUTIONAL BASIS FOR ENACTMENT OF THIS BILL

The constitutional basis for this Bill is provided in Article 2, Section 4, Subsection 1, and Article 50, Section 2 of the Constitution of the Republic of Croatia.

II. POSITION STATEMENT AND KEY ISSUES THAT THIS BILL PROPOSES TO REGULATE, AND EXPECTED IMPACTS OF THE BILL

1. Position Statement

The Republic of Croatia has yet to regulate, either by law or by other regulation, the issues related to the import, placing on the market, use and production of genetically modified organisms and products. Under the Convention on Biological Diversity, ratified by the Republic of Croatia in 1996, the Protocol on Biological Safety provides the obligation of all parties to the Convention to enact the legislation with which they shall regulate the above-referred to issues with respect to genetically modified organisms and products.

The Croatian National Parliament, recognizing the possible impacts of the use of genetically modified organisms and products, on 27 November 1998 passed a Resolution instructing the Government of the Republic of Croatia to appoint a Bioethics Committee and propose the legal framework with respect to this issue. In April 1999, the Government of the Republic of Croatia set up as its advisory body the Bioethics Committee for the monitoring of genetically modified organisms, within the Ministry of Agriculture and Forestry. Furthermore, in April 2001, the Government of the Republic of Croatia appointed a separate National Bioethics Committee for medical issues, under the authority of the Ministry of Health.

The Strategy and the Action Plan for the Protection of Biological and Countryside Diversity of the Republic of Croatia, adopted by the Croatian National Parliament in 1999 (Official Gazette No. 81/99), provided the obligation to enact Genetically Modified Organisms Act. Under Resolution of the Government of the Republic of Croatia of December 2000, the Ministry of Agriculture and Forestry was given mandate to draft a Bill on genetically modified organisms, and to that purpose, a Working Group was appointed which commenced the work on the draft. At the same time, the Ministry of Environmental Protection and Spatial Planning began drafting a Bill on environmental protection and, in accordance with its authority, built into the said Draft Bill the provisions of the Protocol on Biological Safety related to the release of genetically modified living organisms into the environment and their placing on the market, with the aim of protecting the biological diversity.

However, the Draft Bill on environmental protection does not apply to the issues related to the import, use, labeling, handling and transport of genetically modified organisms and products, particularly those that are intended for use as human food. These issues shall be regulated by a separate piece of legislation on foods and food ingredients, the drafting of which is also under way. The Draft Bill on foods is sponsored by the Ministry of Agriculture and Forestry and the Ministry of Health.

Recognizing the possible negative impacts of the import, placing on the market, production and use of genetically modified organisms and products, the Ministry of Health, Ministry of Agriculture and Forestry, Ministry of Environmental Protection and Spatial Planning and the Ministry of Science and Technology propose as an interim solution, until the enactment of a separate piece of legislation that shall regulate the issues related to genetically modified organisms, to impose a ban or restriction on the import, placing on the market, use and production of genetically modified organisms and products.

The area of genetically modified organisms and products is regulated in the European Union by the following legislation:

- Directive 90/219/EEC on the contained use of genetically modified micro-organisms, as amended by Directive 98/81/EEC and Council Directive 2001/204/EC;
- Directive 90/220/EEC on the approval of the deliberate release of genetically modified organisms into the environment, as modified by the following amendments:
    - European Council Directive 94/211/EC;
    - European Commission Directive 92/146/EEC;
    - European Commission Directive 94/15/EC;
    - European Parliament Directive and Council Directive 2001/18/EC which replaced Directive 90/220/EEC;
- EC Regulation No. 258/97 on novel foods and food ingredients;
- EC Regulation 1139/98 on the additional specific details on the labels of foods and food ingredients derived from genetically modified soya and maize;
- EC Regulation No. 49/2000 replacing EC Regulation No. 1139/98;
- EC Regulation No. 50/2000 on the additional requirements for labeling of foods and food ingredients intended for final consumers and mass catering, which contain additives and/or spices that are genetically modified or derived from genetically modified organisms.

All developed European countries have already in place a legal framework for the above referred to issues related to the import, placing on the market or production of genetically modified organisms and products.

Therefore, and recognizing particularly the obligation to preserve and protect the nature and environment, as well as human health. It is essential that the Republic of Croatia regulate this issue by imposing a ban on the import, placing on the market, use or production of genetically modified organisms and products, until such time as the issue may be regulated by appropriate legislation compliant with the international conventions and the European practice.

2. Scope of the Bill

This Bill regulates the following key issues:

1. to impose a ban or restriction on the import, placing on the market, use and production of genetically modified organisms and products;

2. to regulate the issues related to the administrative control and inspection;
3. to designate the legal person responsible for the expert work (laboratory work) related to the tracing of genetically modified organisms;
4. to determine the procedure for disposal of genetically modified organisms and products.

III. ASSESSMENT AND SOURCES OF FUNDS REQUIRED FOR ENFORCEMENT OF THE BILL

The funds required for the enforcement of this Bill amount to HRK 1.600.000,00, specifically for the costs of fitting and equipping the laboratories. The funds in question have already been appropriated from the State Budget for the year 2001, within the appropriate items of the Ministry of Health (HRK 500.000,00), Ministry of Environmental Protection and Spatial Planning (HRK 300.000,00), Ministry of Agriculture and Forestry (HRK 300.00,00) and the Croatian Public Health Institute (HRK 500.000,00). The inspection services competent for the law enforcement shall carry out inspection controls within their scope of authority so that there is no need for additional employment in the government agencies with respect to the activities related to the administrative control and inspection.

In accordance with the above, the enforcement of this Bill does not require any additional appropriations from the State Budget.

IV. LANGUAGE OF THE BILL WITH THE EXPLANATORY MEMORANDUM

The language of this Bill for an Act to ban the import, placing on the market, use and production of genetically modified organisms and products represents the final text of the Bill with the explanatory memorandum.

V. JUSTIFICATION OF THE EMERGENCY PROCEDURE

Under Article 165 of the Rules of Procedure of the House of Representatives of the Croatian National Parliament (Official Gazette No. 9/01), emergency bills may be introduced when such emergency procedure is justified by, among other reasons, particularly important interests of the State.

Recognizing the justifiable concern of the Government with prevention and removal of possible negative impacts on the environment and human health by imposing a ban on the import, placing on the market, use and production of genetically modified organisms and products, the sponsor hereby proposes that this Bill be enacted in an emergency procedure.

A BILL FOR AN ACT TO BAN THE IMPORT, PLACING ON THE MARKET, USE AND PRODUCTION OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS
- FINAL TEXT

Article 1.

(1) The purpose of this Act is to ban the import, placing on the market, use and production of genetically modified organisms and products in the territory of the Republic of Croatia, with the aim of protecting human health, as well as the nature and environment.
(2) The provisions of this Act do not apply to the import, placing on the market, use and production of medicinal drugs, which are regulated by a separate piece of legislation.

Article 2.

For the purpose of this Act, the following legal definitions shall apply:

1. "Organism" is any biological entity, cellular or non-cellular, capable of replication or transferring genetic material, including viruses, viroids and the animal or plant cells in crops;
2. "Genetic modification" means a deliberate alteration of the genetic material of an organism in a way that does not occur by natural recombination, i.e. introduction of a foreign genetic material in the genetic material of an organism or removal of a part of the genetic material of an organism;
3. "Genetically modified organism" means an organism, excepting human beings, whose genetic material has been modified by genetic manipulation;
4. "Product" means a preparation consisting of, and/or containing, one or more genetically modified organisms, regardless of the degree of its processing, intended to be placed on the market.
5. "Contained use" means any use of genetically modified organisms for scientific and/or research purposes, in an area contained by physical barriers or a combination of physical and chemical or biological barriers, used to prevent the contact between genetically modified organisms and the general population and environment.
6. "User" means any legal or natural person, who imports, places on the market, uses or produces genetically modified organisms and products.

Article 3.

(1) A ban is hereby imposed on the import, placing on the market, use and production of genetically modified organisms.
(2) Notwithstanding the provision from Paragraph 1 above, the import, use and/or production of genetically modified organisms may be approved for the purpose of conducting scientific research, provided that the user warrants and ensures a contained use of such organisms.

Article 4.

(1) An approval of the import, use and/or production in accordance with Article 3, Paragraph 2 above, following the application submitted by a legal person, may be issued by the minister of science and technology, based on a prior consent issued by the minister of health, minister of environmental protection and spatial planning and the minister of agriculture and forestry.
(2) The approval procedure from Paragraph 1 above shall be defined by the law enforcement regulation issued by the minister of science and technology.

Article 5.

(1) Administrative control with respect to the enforcement of this Act shall be conducted by the Ministry of Health, Ministry of Environmental Protection and Spatial Planning, Ministry of Agriculture and Forestry and the Ministry of Science and Technology, each within its scope of authority.
(2) The inspection control over the enforcement of this Act shall be carried out by official inspection services for food safety, animal health and plant cultivation, border inspection services for plant health, environmental inspection services, as well as by the economic inspection offices of the State Inspectorate, each within its own scope of authority, in compliance with separate regulations.

Article 6.

(1) If the competent inspection authority has grounds to believe that a genetically modified organism or product is being imported, placed on the market, used or produced, the said inspection authority shall demand the user to present valid documentation verifying that the organism or product in question has not been genetically modified.
(2) If the user fails to present valid documentation within the prescribed period of time, the competent inspector shall temporarily prohibit the import, use and/or production, and sample the organism or product in question for analysis in a designated laboratory.
(3) The competent laboratories from Paragraph 2 above, shall be designated by the minister of health.
(4) The competent laboratories from Paragraph 2 above shall meet the criteria stipulated by the law enforcement regulation issued by the minister of health, based on the consent issued by the minister of environmental protection and spatial planning, minister of agriculture and forestry and the minister of science and technology.
(5) If the analysis confirms that the organism and/or product in question has been genetically modified, the inspector shall permanently prohibit the import, placing on the market, use or production of such organism and/or product, and the samples, or the confiscated genetically modified organisms and products, shall be safely disposed of.
(6) If the analysis confirms that the organism and/or product in question is a genetically modified organism and/or product, the costs of analysis and safe disposal, as well as the costs of the interim safekeeping and custody, shall be borne by the user.

Article 7.

(1) Any legal or natural person found importing, placing on the market, using and/or producing genetically modified organisms and products contrary to the provisions of this Act, shall pay a fine in the amount of HRK 100.000,00 to HRK 500.000,00.
(2) The responsible natural person within the legal person from Paragraph 1 above, shall pay a fine in the amount of HRK 20.000,00 to HRK 60.000,00.
(3) Genetically modified organisms and products that are the subject of the violation from Paragraph 1 above, shall be confiscated.

Article 8.

(1) Any legal person who has commenced scientific research in the area of genetic modification prior to the commencement of this Act, shall notify the Ministry of Science and Technology of such research within a period of forty-five days after the commencement of this Act.
(2) The Ministry of Science and Technology shall inform the Ministry of Health, Ministry of Environmental Protection and Spatial Planning and the Ministry of Agriculture and Forestry of such research projects in the area of genetic modification, within a period of fifteen days after the expiration of the deadline from Paragraph 1 above.
(3) The decision on the approval or termination of the scientific research from Paragraph 1 above, shall be made by the Ministry of Science and Technology, with the consent of the Ministry of Health, Ministry of Environmental Protection and Spatial Planning and the Ministry of Agriculture and Forestry, within a period of sixty days after the receipt of the notification from Paragraph 1 above.
(4) If the decision on the approval or termination is not made within the deadline stipulated by Paragraph 3 above, the approval shall be deemed given.

Article 9.

In the event that this Act grants the authority to the competent minister to approve the regulation for the enforcement of this Act, the competent minister in question shall approve the said regulation within a period of three months after the commencement of this Act.

Article 10.

This Act shall take effect on the date of its publication in the Official Gazette.

EXPLANATORY NOTES TO CERTAIN PROVISIONS OF THIS ACT

Note to Article 1.
The provisions of Article 1 define the scope of this Act, specifically the ban on the import, placing on the market, use and/or production of genetically modified organisms and products in the territory of the Republic of Croatia, aimed at protection of human health, the nature and environment. This Article expressly exempts medicinal drugs from the scope of this Act, as the products in question are regulated by a separate piece of legislation.

Note to Article 2.
Article 2 provides the legal definitions of the terms used in this Act.

Note to Article 3.
Article 3 stipulates the ban on the import, placing on the market, use and production of genetically modified organisms and products, and exempts from the ban the import, use and production of the genetically modified organisms and products intended for scientific research. This Article also provides the criteria for the approval of the import or use of the genetically modified organisms intended for scientific research.

Note to Article 4.
The provisions of this Article provide the authority for the approval of the import, use and/or production of the genetically modified organisms intended for scientific and research purposes.

Note to Article 5.
This Article stipulates the administrative control and inspection authorities with respect to the enforcement of this Act.

Note to Article 6.
The provisions of this Article stipulate the procedure and the authority of the competent inspector if there is sufficient grounds to believe that a genetically modified organism or product is being imported, placed on the market, used and/or produced; stipulate the method of determining the competent legal person to conduct the analysis of the same; and grant the authority to the competent inspector to undertake measures if the analysis confirms that a genetically modified organism or product is being imported, placed on the market, used and/or produced. If analysis confirms that genetically modified organisms or products are being imported, placed on the market, used and/or produced, the provisions of this Article stipulate that the costs of analysis and safe disposal, and in certain cases the costs of safekeeping and custody, of the organisms or products in question shall be borne by the user.

Note to Article 7.
This Article stipulates the acts in violation of the provisions of this Act and provides the fine for those found in violation, and stipulates the confiscation of the organism or product that is the subject of the violation.

Note to Article 8.
This Article stipulates that any legal person who has commenced scientific research prior to the commencement of this Act, must notify the Ministry of Science and Technology; stipulates

deadlines for procedures, as well as the procedure for the approval or termination of the research, and the authority of the state administration bodies with respect to the approval procedure.

Note to Article 9.
This Article provides the authority to adopt law enforcement regulations and stipulates the deadline for their adoption.

Note to Article 10.
This Article stipulates when this Act shall commence.